Guidance on the Use of Residue Chemistry Review Templates

Date: September, 2003

Introduction

This document provides guidance on the use of the data evaluation records (DERs) for residue chemistry data reviews. This guidance is additional to that already present in the DER templates themselves. The residue chemistry templates have been developed to standardize data reviews within HED and between HED and our NAFTA partners. Templates have been developed for each US EPA guideline in the 860 series and each PMRA DACO in Directive 98-02 that require data review and/or summary:

860.1200	DACO 1.0	Directions for Use;
860.1300	DACO 6.2, 6.3	Nature of the Residue -- Plants and Livestock;
860.1340	DACO 7.2.1, 7.2.2, 7.2.3	Residue Analytical Method;
860.1360	DACO 7.2.4	Multi-residue Method;
860.1380	DACO 7.3	Storage Stability Data;
860.1400	DACO 6.4, 7.4, 7.8	Water, Fish, and Irrigated Crops;
860.1460	DACO 7.8	Food Handling;
860.1480	DACO 7.5.1	Meat, Milk, Poultry, and Eggs;
860.1500	DACO 7.4.1, 7.4.2	Crop Field Trials;
860.1520	DACO 7.4.5	Processed Food and Feed;
860.1850	DACO 7.4.3	Confined Accumulation in Rotational Crops;
860.1900	DACO 7.4.4	Field Accumulation in Rotational Crops.

For U.S. EPA use, there is also a document template for the residue chemistry summary document (i.e., chemistry chapter).

DER PARADIGM

One of the fundamental differences between the DER-approach to residue chemistry review and the old chemistry review documents is the separation of science decisions in the DERs from the regulatory recommendations in the summary document. Separating science from regulation allows the DERs to be uninfluenced by changes in use patterns, use sites, or policy. As those changes occur, only the summary document will need to be updated to reflect the current regulatory conditions. Furthermore, restricting DERs to science evaluation allows the possibility of submission of DERs by the regulated community, thus streamlining the review process, and allowing the scientists to focus on residue chemistry.

GENERAL REMARKS

Typically, each study received by HED will be reviewed in a separate template, although certain studies may be combined in order to avoid redundancy (e.g., combining magnitude of residue and residue decline data). Reviewers should *not* combine studies across guidelines. Though one of the goals of the templates is to standardize reviews within HED, the templates should be viewed as being flexible. The level of detail in some sections of the templates, including tables, may be increased or decreased depending on the needs of individual chemicals; however, the executive summary section is specifically designed to be inserted into the residue chemistry chapter. The reviewer should keep in mind that long executive summaries will result in longer residue chemistry chapters. Reviews should not include excessive details regarding non-pertinent information. In all cases, the content of a data review must be sufficient to adequately characterize the submitted data.

Note: The reviewer should keep in mind that the tables included in the templates are a starting place and should be modified as needed; however, if a table does not apply, then the reviewer should place "Not Applicable" in the first row and delete subsequent rows. To maintain consistent table numbering, do not delete the tables. In some cases, the study may require additional tables. When adding tables, please follow the table numbering scheme in the DER template and accommodate the new tables by adding an additional digit to the table number (e.g., if Table C.3.1 needs to be split into two tables, they should be numbered C.3.1.1 and C.3.1.2).

COMMON ELEMENTS

Headers and Footers

Each template has a header that contains the name of the active ingredient, PC code, company name, as well as the type of study and guideline numbers for PMRA, EPA, and OECD. Each template also has a footer that contains page numbering and tracking information for PMRA and EPA. If this is not a joint review, the information in the header and footer not pertinent to your country should be deleted.

Note: Each DER contains a Part F which captures review dates and tracking information (DP Barcode, PC Code, petition numbers, etc.). Although the tracking information also appears in the header and footer, it is repeated in the main body of the document for EPA electronic document management purposes. This information is only pertinent to the EPA.

Signature Block

This section is fairly self explanatory and laid out as a table. Rows should be added to accommodate the peer review stream. Part F of the templates contains an RDI line for capturing review dates electronically. Dates should be hand written in the signature block on the final copy of the DER. In the case of a joint review, multiple copies of the signature pages are required so that each country involved in the joint review will have a DER with an original signature page. Also, the evaluation team should discuss the requirements for single-sided printing and any other formatting issues.

Executive Summary

The executive summary should provide enough detail that it can be used in EPA's summary document (residue chemistry chapter) and in PMRA's regulatory decision document without modification. If necessary, the executive summary may be expanded from the model provided in the template to meet the needs of the chemical.

Study/Waiver Acceptability/Deficiencies/Clarifications

This section of the DER summarizes the scientific acceptability of the study and serves as a place to discuss scientific deficiencies or areas that require clarification. This section also contains a reference to the upcoming summary document within which regulatory recommendations will be made.

Compliance

For the compliance section, the discussion should focus on non-GLP items and their impact on the conclusions or acceptability of the study.

Science Sections

Each DER contains sections for Experimental Design (or Materials and Methods for methods DERs), Results and Discussion, and Conclusions. Within each section, the reviewer should not include information pertinent to other sections. For example, in the Experimental Design section, the reviewer should not include results, a discussion of the results, or any conclusions. The conclusion section should focus on the scientific "bottom line" of the review and not be a re-hash of the entire study or a copy of the executive summary.

Note: Many of the DERs contain a section in which the analytical method is described. In

most cases, the method will be the data-gathering and/or tolerance-enforcement method that is addressed by an Analytical Method DER. When a method is fully reviewed in its own DER, the DER for the study that relies on that method should contain only a short characterization of the suitability of the method and a reference to the supporting DER. Of course, if the method is not addressed elsewhere, it will need a full description and characterization in the study's DER.

GUIDANCE ON INDIVIDUAL GUIDELINES

OPPTS 860.1200 Directions for Use
DACO 1.0

The Directions for Use DER is not a true DER in that there is no study to review. This document summarizes the use patterns for the chemical and in Canada this is based on the efficacy and vaue review by ESAD. Although EPA does not routinely complete the Directions for Use DER, it is a useful tool for data exchange during joint reviews and some Branch Senior Scientists may find the information helpful when reviewing DERs prior to completion of the residue chemistry summary document.

OPPTS 860.1300 Nature of the Residue -- Plants and Livestock
DACO 6.2, 6.3

The Nature of the Residue DERs are more "open" due to the complexity of metabolism studies. For these studies in particular, the reviewer should consider the templates as a starting point for writing their review; however, the general structure of the templates should not be altered. The metabolism flowchart (FIGURE C.3.1.) is required. Flow charts may be generated by using VISIO or ISIS Draw, available at:

http://www.mdl.com/downloads/isis.draw/isisdrawreg.html

Radioisotope data are often reported in units of microCuries (μCi) or, less frequently, disintegrations per minute (dpm). The official SI unit for reporting radioactivity is the Bequerel (Bq). A Bq is defined as a disintegration per second. To convert from dpm to Bq, divide by 60. To convert from Ci to Bq, multiply by 3.7×10^{10}.

OPPTS 860.1340 Residue Analytical Method
DACO 7.2.1, 7.2.2, 7.2.3

Section B.1.1 and Section B.2.1 - Principle of the Method. In the descriptive paragraph, include the principles of the method with respect to extraction and cleanup procedures and the principles of analyte detection and quantitation (e.g., HPLC/UV, GC/MS, etc.). Details regarding the instrument, column, and/or detector parameters are included in the table and do not need to be reproduced in the text. For EPA, note whether or not analytical standards have been supplied to the Pesticide Standards Repository at the Analytical Chemistry Branch.

OPPTS 860.1360 Multi-residue Method
DACO 7.2.4

The residue chemist should provide a summary of protocols that were used and the resulting recoveries. Note, EPA does not officially evaluate the suitability of the multi-residue methods.

Some older reports may list procedures as Protocols I - IV. If such is the case, translate these to the letter protocols (A-G) using the information on FDA's PESTRAK website:

http://www.cfsan.fda.gov/~frf/pestdata.html

OPPTS 860.1380 Storage Stability Data
DACO 7.3

This DER is fairly self-explanatory. If you have questions, please see someone from the EPA Residue Chemistry Templates Workgroup, or the PMRA Workgroup Lead.

OPPTS 860.1400 Water, Fish, and Irrigated Crops
DACO 6.4, 7.4, 7.8

The Water, Fish, and Irrigated Crops DER is also more "open" due to the complexity of the studies. For this guideline, the reviewer should consider the templates as a starting point for writing their review; however, the general structure of the templates should not be altered. The metabolism flowchart (FIGURE C.3.1.) is required.

Radioisotope data are often reported in units of microCuries (μCi) or, less frequently, disintegrations per minute (dpm). The official SI unit for reporting radioactivity is the Bequerel (Bq). A Bq is defined as a disintegration per second. To convert from dpm to Bq, divide by 60. To convert from Ci to Bq, multiply by 3.7×10^{10}.

OPPTS 860.1460 Food Handling
DACO 7.8

This DER is fairly self-explanatory. If you have questions, please see someone from the EPA Residue Chemistry Templates Workgroup, or the PMRA Workgroup Lead.

OPPTS 860.1480 Meat, Milk, Poultry, and Eggs
DACO 7.5.1

For EPA, dietary burden calculations should not be included in the DER. Because dietary burdens may change as use sites are added or removed, the dietary burden calculations and discussion are better suited to the summary document. However, for a PMRA or joint-review DER, the dietary burden calculations should be included as an appendix. It must be made clear that the dietary burden in the appendix may not be valid at a future time. Note that an Excel spreadsheet is available for calculating the dietary burden.

The DER template has been set up to assume that most residue-feeding level dependencies are best described by a linear relationship. The reviewer should determine, for each livestock matrix, the most appropriate relationship between residues and feeding level. For Figure C.2, alter the figure title to accurately describe the relationship between residue levels and feeding level. Software packages are available to work with many different linear and non-linear regression models (JMP, EXCEL, SYSTAT, etc.).

OPPTS 860.1500 Crop Field Trials
DACO 7.4.1, 7.4.2

The Crop Field Trial template is designed to be used for both magnitude of the residue data and residue decline data. If the data are submitted in the same study, it is not necessary to generate a separate residue decline DER.

Site-Specific Information. Specific data regarding cultivation, irrigation, fertilizer and maintenance chemicals, and weather must be provided if they impact the results of the study. In most cases, the information requested in the site characterization table is sufficient.

OPPTS 860.1520 Processed Food and Feed
DACO 7.4.5

The template calls for a flowchart of the processing procedures. This should only be included if supplied electronically. If the procedures are not provided in a graphic, the reviewer will need to include a text-based description of the processing procedures or generate their own graphic representation.

OPPTS 860.1850 Confined Accumulation in Rotational Crops
DACO 7.4.3

The Confined Accumulation in Rotational Crops DER is also more "open" due to the complexity of radio-labeled studies. For these studies in particular, the reviewer should consider the templates as a starting point for writing their review; however, the general structure of the templates should not be altered. The metabolism flowchart (FIGURE C.3.1.) is required. Flow charts may be generated by using VISIO or ISIS Draw, available at:

http://www.mdl.com/downloads/isis.draw/isisdrawreg.html

Radioisotope data are often reported in units of microCuries (μCi) or, less frequently, disintegrations per minute (dpm). The official SI unit for reporting radioactivity is the Bequerel (Bq). A Bq is defined as a disintegration per second. To convert from dpm to Bq, divide by 60. To convert from Ci to Bq, multiply by $3.7x10^{10}$.

OPPTS 860.1900 Field Accumulation in Rotational Crops
DACO 7.4.4

Site-Specific Information. Specific data regarding cultivation, irrigation, fertilizer and maintenance chemicals, and weather must be provided if they impact the results of the study. In most cases, the information requested in the site characterization table is sufficient.

GUIDANCE ON SUMMARY DOCUMENTS

The residue chemistry summary document (EPA), and the note to file and the Regulatory Decision Document (PMRA) are equivalent to the residue chemistry chapter under the DER paradigm. It ties the scientific data, use patterns, and HED policies together into a regulatory framework. It is at this level of integration that weight-of-the-evidence decisions can be made regarding data gaps in a chemical's residue chemistry database, the impact of those data gaps on HED's regulatory recommendations, and the need for additional data.

The summary document should consist of an executive summary, a list and discussion of deficiencies, a brief introduction with background regulatory information, a summary of each of the residue chemistry guideline area, as well as a discussion of the proposed/recommended tolerances/MRLs, and any international harmonization issues. For EPA, the content of the executive summary is based on the residue chemistry portions of the human health risk assessment and provides an efficient way to transfer the residue chemistry picture to the risk assessment document.

For each guideline topic, include the executive summaries from the DERs and an overall regulatory conclusion. For nature of the residue, chemists are encouraged to provide an overall summary of the metabolism of the chemical in target crops, livestock, and rotational crops rather than individual DER summaries. The metabolism summary may be taken from the MARC briefing memo if available. In addition, the summary document should clearly state the residues of concern for the tolerance expression and risk assessment, as well as the supporting rationale. For livestock feeding studies, evaluators should provide the dietary burden calculations used for tolerance-setting purposes (an Excel spreadsheet is available for calculating maximum theoretical dietary burden). The feeding study section may also include the dietary burden calculations used for deriving livestock anticipated residues.

HELPFUL HINTS

Graphics in WordPerfect - The residue chemistry DERs contain more figures than previous chemistry reviews. The default setting for graphic boxes in WordPerfect is to have the box attached to the page and to have text wrapping in a square pattern around the box. When a document is edited, these settings can result in the figure moving to unintended places in the document. Changing the attachment setting to "paragraph" and the wrap setting to "neither side" will minimize this problem. The default settings can be changed to the suggested settings by selecting from the main menu Format, Graphics Styles, Image Box, Edit, Position to attach box to paragraph, and Wrap Text to neither side. Additionally, placing multiple figures on one page in WordPerfect can be problematic. When possible, use other software, such as Microsoft Excel or PowerPoint, to group the figures together before pasting them into WordPerfect. Finally, when pasting figures (including chemical structures), use the Paste Special function in WordPerfect and paste the graphic as a picture. This will avoid OLE and other compatibility errors.

Summary Statistics - Many of the DERs have a residue summary table that contains the number of data points, minimum residue, maximum residue, median residue, average residue, standard deviation, and highest average field trial (HAFT) for each distinct use pattern within the study. Other than the HAFT, these summary statistics can be fairly easily obtained using JMP or SYSTAT statistical software or the Pivot Table feature of Microsoft Excel. As a reminder, the median is equivalent to the 50^{th} percentile (middle value) in the distribution. When there is an odd number of numbers, the median is simply the middle number. When there is an even number of numbers, the median is the mean of the two middle numbers. Typically, there are multiple residue values for each trial location. When residue values are averaged for each field trial site, one of the sites will have the highest average. That number is the HAFT.

Dietary Burden Calculations - A Microsoft Excel spreadsheet is available to help calculate livestock dietary burdens based on information in OPPTS 860.1000 Table 1, and Dir98-02 (Section 8).

EPA FILING PROCEDURES

Completed DERs and summary documents are handled in the same manner as other reviews: completed documents (in signed paper and electronic WordPerfect format) are forwarded to IMCSB in the HED plum folder system for division log out and HED Records Reference Center purposes. Electronic files should be named as follows:

> **DERs:** The main MRID number addressed by the DER, followed by ".DER.wpd" (e.g., 98765432.DER.wpd). Occasionally there may be multiple DERs for a single MRID. Such a situation would occur when a single submission addresses multiple guidelines (e.g., a crop field trial study report that includes a storage stability study and/or a processing study. When this occurs, the DER portion of the file name should be changed to DE1, DE2, DE3, etc. (e.g., 98765432.DER.wpd, 98765432.DE1.wpd).
>
> **Summary document:** The DP Barcode for the summary document followed by document type and ".wpd." For example, ".mem.wpd" (e.g., D278435.mem.wpd) or ".RED.wpd" (e.g., D278435.RED.wpd).

Completed template reviews are stored only in the **OPP Chemistry Database**, and **will not be filed to the T:drive or the Residue Chemistry Notes Database**. Prior to submitting documents via the plum folders, reviewers must open a new record in the OPP Chemistry Database and complete the requested information. A new record can be created by clicking on the "Create a Chemistry Record" button. A printed copy of the Notes record should be placed in the plum folder. Any files that are to be attached to the record will need to be supplied on either a floppy disk or a Zip disk if a floppy does not have enough storage space. File should not be submitted in compressed (i.e. "zipped") format.

PMRA FILING PROCEDURES

Completed DERs should be filed in the 0-draft (X:/HED/FREAS/ag_chems/0-draft). Once the DERs are signed, they will be moved to the final draft under the respective active ingredient folder. A copu of the DERs should be placed in the workbook, with the exception of the dietary risk assessment template.

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

END-USE PRODUCTS:

Table 1. Summary of End-Use Products

Trade Name	Reg. No.	a.i. (% of formulation)	Formulation Type	Target Crops	Target Pests	Label Date

Table 2. Summary of Directions for Use of Chemical Name.

Trade Name	Applic. Timing, Type, and Equip.	Applic. Rate (lb a.i./A) (g a.i./ha)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb a.i./A) (g a.i./ha)	PHI (days)	Use Directions and Limitations
Commodity 1						
Commodity 2						
Commodity 3						

CONCLUSION

[Are the labels adequate to allow evaluation of the residue data relative to the proposed use? Are there label additions/revisions/clarifications that are recommended? Summarize any label deficiencies and characterize their impact on the regulatory recommendations for this action.]

REFERENCES

DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical name, % a.i., formulation type, include location of radioactive label, specific activity] was applied to [seed (seed treatment), soil (preplant incorporated) or crop (growth stage)] at [rate of application (g a.i./100 kg seed or g a.i./ha)]. [Include details of testing environment (i.e., outdoor test plots, greenhouse, plant growth chambers, hydroponics, etc.). In a few sentences, describe the extraction and characterization techniques that were used to analyze residues in the plant matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study.]

[Describe the major residue(s) (i.e., > 0.1 ppm or > 10% of the TRRs) in plant matrices. This description should include the identity and distribution of the residues in the plant and the residue levels (ppm parent-equivalents and % of the TRRs).

[Briefly discuss routes of translocation from the point of application; radioactivity plant parts of concern (absorption/distribution/disposition), especially as it relates to sequestration of residues in tissues; extractability. recoveries/account abilities.]

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the plant metabolism data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed to accommodate multiple test compound]

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapour pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Test Site and Crop Information

TABLE B.1.1. Test Site Information				
Testing Environment*	Soil characteristics**			
	Type	%OM	pH	CEC

* outdoor test plots, greenhouse, plant growth chambers, etc
** Only required for studies involving a soil treatment

Explain any meteorological abnormalities that may have impacted the study.

TABLE B.1.2. Crop Information					
Crop/crop group	Variety	Growth stage at application	Growth stage at harvest	Harvested RAC	Harvesting procedure

B.2. Test Materials

TABLE B.2.1. Test Material Characteristics		
Chemical structure	[Insert structure]	[Insert structure]
Radiolabel position		
Lot No.		
Purity		
Specific activity (Bq)*		

* Bq = disintegrations per second

B.3. Study Use Pattern

TABLE B.3.1. Use Pattern Information	
Chemical name	
Application method	
Application rate	
Number of applications	
Timing of applications	
PHI	

B.4. Identification/ Characterization of Residues

B.4.1. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

[If available, include a graphic (i.e., flowchart) of the extraction and fractionation schemes.]

[Briefly describe the extraction, fractionation and hydrolysis strategies for each tissue. The description should including solvents used (ratios), the order of their use, the extraction procedures employed (i.e., blending, maceration, Soxhlet, etc.) and procedures used to release bound and conjugated residues (i.e., acid, base, or enzyme hydrolysis, exhaustive extraction, etc.). Has the petitioner justified the use of severe conditions (e.g., strong acid hydrolysis in the presence of heat, etc.).]

B.4.2. Analytical Methodology

[Briefly describe the methods used for identification/characterization of the residues (LSC, TLC, GLC, HPLC, etc.). If applicable, very briefly describe difficulties with methods that fail to elucidate the nature of the residues or bound residues as in lignin, cellulose, protein solubilization methodologies.]

C. RESULTS AND DISCUSSION

[Insert graphical representation of results to highlight trends in the data, if any, and reference all tables in the relevant part of the discussion. This should not be identical to the Executive Summary or Conclusion.]

[Discuss the adequacy of the storage stability data.]

[Described the methods used to conduct the metabolism study and to analyze the residues. Discuss any impact that the methods *per se* may have had on the results. Discuss the method's ability to extract the predominant residues from the various plant matrices. Report the accountability. Has the petitioner demonstrated that residues are stable during storage?]

[Describe the residues in terms of levels, location in the plant (i.e., partitioning into leaves/stems/roots; i.e., is the chemical systemic, including the effects of any variation in application techniques). Point out the predominant residues. Note that this is a stand-alone evaluation of the metabolism study. As such, it is not appropriate to discuss residues of concern in this document.]

C.1. Storage Stability

TABLE C.1. Summary of Storage Conditions			
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Study Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

C.2. Identification, Characterization, and Distribution of Residues

TABLE C.2.1. Total Radioactive Residues (TRRs) in [Matrices].				
Matrix	Timing and Applic. No.	PHI (days)	Radiolabel position	Radiolabel position
			ppm	ppm

TABLE C.2.2. Distribution of the Parent and the Metabolites in Plant Matrices when Dosed with ^{14}C-labeled Test Compound X. [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental design.]

Metabolite Fraction	Matrix 1		Matrix 2		Matrix 3	
	%TRR	ppm	%TRR	ppm	%TRR	ppm
Surface wash						
[Add a row for each identified compound]						
[Unidentified compound]						
Organosoluble						
[Add a row for each identified compound]						
[Unidentified compound]						
Aqueous soluble						
[Add a row for each identified compound]						
[Unidentified compound]						

Table C.2.3. Summary of Characterization and Identification of Radioactive Residues in Plant Matrices Following Application of Radiolabeled [Chemical] at [Rate]. [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental design.]

Compound	Matrix 1		Matrix 2		Matrix 3	
	% TRR	ppm	% TRR	ppm	% TRR	ppm
[Parent]						
[Metabolite 1]						
[Metabolite 2]						
[Metabolite 3]						
[Metabolite 4]						
Total identified						
Total characterized						
Total extractable						
Unextractable (PES)[1]						
Accountability[2]						

[1] Residues remaining after exhaustive extractions.

[2] Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis; see TABLE C.2.1) * 100.

C.3. Proposed Metabolic Profile

FIGURE C.3.1. Proposed Metabolic Profile of [Chemical] in [Crops]

[Insert metabolic profile]

TABLE C.3.1. Identification of Compounds from Metabolism Study

Common name/code Figure C.3.1 ID No.	Chemical name	Chemical structure

D. CONCLUSION

[Summarize the results of the submitted plant metabolism studies such as: routes or pathways, mechanisms involved and extent/degree of metabolism observed, nature, amount, and distribution of the TRRs in the plant tissues. This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical name, %a.i., formulation, include location of radioactive label; specific activity] was administered to [(# of animals) species, strain]/dose at dose levels of [x] mg/kg bw/day. [Describe how the dose was administered/applied (e.g. oral, dermal, etc.). In a few sentences, describe the extraction and characterization techniques that were used to analyze residues in the livestock matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study.]

[Describe the major residue(s) (i.e., > 0.1 ppm or > 10% of the TRRs) in livestock matrices. This description should include the identity and distribution of the residues in the animal and the residue levels (ppm parent-equivalents and % TRR).]

[Discuss recoveries/accountabilities and routes of elimination of radioactivity; absorption and excretion of the compound; radioactivity in organs of concern (distribution/disposition), especially as it relates to sequestration of residues in tissues; extractability; major metabolites; other major factors.]

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the livestock metabolism data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapour pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Livestock

TABLE B.1.1. General Test Animal Information					
Species	Breed	Age	Weight at study initiation (kg)	Health Status	Description of housing/holding area

TABLE B.1.2. Test Animal Dietary Regime				
Composition of Diet	Feed consumption (kg/day)	Water	Acclimation period	Predosing

TABLE B.1.3. Test Animal Dosing Regime			
Treatment Type	Feeding Level (ppm test material in food)	Vehicle	Timing/Duration
Oral, dermal, aquaculture		capsule, feed, bolus, etc.	

B.2. Test Materials

TABLE B.2.1. Test Material Characteristics		
Chemical structure	Insert Structure	Insert Structure
Radiolabel position		
Lot No.		
Purity		
Specific activity (Bq)*		

*Bq = disintegrations per second

B.3. Sampling Information

TABLE B.3.1. Sample Collection Information			
Milk/Eggs collected [Note: Include quantity of milk/ eggs produced during normal production.]	Urine, feces and cage wash collected*	Interval from last dose to sacrifice	Tissues harvested and analysed
XXX daily	XXX daily	XXX hours	

*If available.

B.4. Identification/ Characterization of Residues

B.4.1. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

[If warranted, include a graphic (i.e., flowchart) of the extraction and fractionation schemes and omit following textual description.]

[Briefly describe the extraction, fractionation and hydrolysis strategies for each tissue. The description shoul including solvents used (ratios), the order of their use, the extraction procedures employed (i.e., blending, maceration, Soxhlet, etc.) and procedures used to release bound and conjugated residues (i.e., acid, base, or enzyme hydrolysis, exhaustive extraction, etc.). Has the petitioner justified the use of severe conditions (e.g., strong acid hydrolysis in the presence of heat, etc.).]

B.4.2. Analytical Methodology

[Briefly describe the principle of the methods used for identification/characterization of the residues. Specify instrumentation (LSC, TLC, GLC, HPLC, etc.) and detection method used (UV, ECD, FID, MS/MS, etc.). State the LOD and LOQ. If applicable, very briefly describe difficulties with methods that fail to elucidate the nature of the residues or bound residues as in protein or lipid fractions.]

C. RESULTS AND DISCUSSION

[Insert graphical representation of results to highlight trends in the data, if any, and reference all tables in the relevant part of the discussion. This section should not be identical to the Executive Summary or the Conclusions.]

[Discuss the adequacy of the storage stability data.]

[Describe the methods used to conduct the metabolism study and to analyze the residues. Discuss any impact that the methods *per se* may have had on the results. Discuss the method's ability to extract the predominant residues from the various livestock matrices. Report the accountability. Has the petitioner demonstrated that residues are stable during storage?]

[Describe the residues in terms of levels, location in the livestock matrices (i.e., partitioning into fat vs. muscle vs. milk, etc.). Point out the predominant residues. Note that this is a stand-alone evaluation of the metabolism study. As such, it is not appropriate to discuss residues of concern in this document.]

C.1. Storage Stability

TABLE C.1. Summary of Storage Conditions			
Matrix	Storage Temp.(˚C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

C.2. Identification, Characterization, and Distribution of Residues

TABLE C.2.1. Total Radioactive Residues (TRRs) in Milk/Eggs, Tissue and Excreta			
Matrix	Collection Timing	Specify position of label-1	Specify position of label-2
		ppm	ppm
Urine*			
Feces*			
Muscle			
Fat			
Kidney			
Liver			
Milk/Eggs			
Upper GI tract			
Lower GI tract			
Other			
% of Administered Dose			

*If available

FIGURE C.2.1. Pharmacokinetics of [Chemical] in Excreta and [Milk/Eggs] of [Lactating Goat/Laying Hen]

[Insert figure showing profile of TRR with time]

TABLE C.2.2. Distribution of the Parent and the Metabolites in Livestock Matrices when Dosed with ^{14}C-labeled Test Compound X. [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental design.]

Metabolite Fraction	Urine*		Feces*		Muscle		Fat		Kidney		Liver		Milk/Eggs	
	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm
Surface wash														
[Add a row for each identified compound]														
[Unidentified compound]														
Organosoluble														
[Add a row for each identified compound]														
[Unidentified compound]														
Aqueous soluble														
[Add a row for each identified compound]														
[Unidentified compound]														

*If available.

Table C.2.3. Summary of Characterization and Identification of Radioactive Residues in Livestock Matrices Following Application of Radiolabeled [Chemical] at [Rate]. [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental design.]

Compound	Muscle		Fat		Kidney		Liver		Milk/Eggs	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	%TRR	ppm
[Parent]										
[Metabolite 1]										
[Metabolite 2]										
[Metabolite 3]										
[Metabolite 4]										
Total identified										
Total characterized										
Total extractable										
Unextractable (PES)[1]										
Accountability[2]										

[1] Residues remaining after exhaustive extractions.

[2] Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis; see TABLE C.2.1) * 100.

C.3. Proposed Metabolic Profile

FIGURE C.3.1. Proposed Metabolic Profile of [Chemical] in [Lactating Goat/Laying Hen]

[Insert metabolic profile]

TABLE C.3.1. Identification of Compounds from Metabolism Study

Common name/code Figure C.3.1 ID No.	Chemical name	Chemical structure

D. CONCLUSION

[Summarize the results of the submitted livestock metabolism studies such as: routes or pathways, mechanisms involved and extent/degree of metabolism observed, nature, amount, and distribution of the TRRs in the tissues, milk/eggs. This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Briefly identify (e.g., method number) and describe the analytical method, including the extraction/cleanup/analysis strategies, the analytes that the method will quantify, and the limits of detection and quantification. Provide a summary of the recoveries obtained by the method and the acceptability of the method. Has the method been shown to be specific to the target analyte(s) by either interference testing with other pesticides or through the use of specific detectors (e.g., GC/MS, HPLC/MS/MS).]

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, analytical method test data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. MATERIALS AND METHODS

B.1. Data-Gathering Method

B.1.1. Principle of the Method:

[Briefly describe the method used to detect the analytes in matrices.]

TABLE B.1.1. Summary Parameters for the Analytical Method Used for the Quantitation of [Chemical] Residues in [Matrices].	
Method ID	
Analyte(s)	
Extraction solvent/technique	
Cleanup strategies	
Instrument/Detector	
Standardization method	
Stability of std solutions	
Retention times	

B.2. Enforcement Method

[If the enforcement method is the same as the data-gathering method, state that the method is the same and delete the rest of Section B.2.]

B.2.1. Principle of the Method:

[Briefly describe (including method type, detection type and column) the method used to detect the analytes in the crop matrices.]

TABLE B.2.1. Summary Parameters for the Analytical Enforcement Method Used for the Quantitation of [Chemical] Residues in [Matrices].	
Method ID	
Analyte(s)	
Extraction solvent/technique	
Cleanup strategies	
Instrument/Detector	
Standardization method	
Stability of std solutions	
Retention times	

C. RESULTS AND DISCUSSION

C.1. Data-Gathering Method

TABLE C.1.1. Recovery Results from Method Validation of [matrices] using the Data-Gathering Analytical Method. Standards were prepared in [solvent]			
Matrix	Spiking Level (mg/kg)	Recoveries Obtained	Mean Recovery ± SD (CV)

[Discuss the suitability of extraction solvent(s) and recovery results obtained with that of the metabolism (%TRRs) studies. Is the method adequate to bracket the expected residue levels. Has the petitioner proposed a confirmatory method or is the method specific (e.g., GC/MS, LC/MS/MS) to the analytes of interest? Was an interference study conducted.]

TABLE C.1.2. Characteristics for the Data-Gathering Analytical Method Used for the Quantitation of [Chemical] Residues in [Matrices].	
Analyte	
Equipment ID	
Limit of quantitation (LOQ)	
Limit of detection (LOD)	
Accuracy/Precision	[range of percent recoveries ± coefficient of variation (specify range) indicating acceptable/unacceptable accuracy/precision in the range of spiking levels (x).]
Reliability of the Method/ [ILV]	[An independent laboratory method validation [ILV], method No. AAA , was conducted to verify the reliability of method No. AAA for the determination of (pesticide) residues in [matrices]. The values obtained are indicative that method No. is reliable].
Linearity	[The method/detector response was linear (coefficient of determination, r^2= 0.xxx) within the range of xxx - yyy ppm.]
Specificity	[The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest. Peaks were well defined and symmetrical. There appeared to be no carryover to the following chromatograms].

C.2. Enforcement Method

If the enforcement method is the same as the data-gathering method, state that the methods are the same and omit the remainder of Section C.2. [Discuss the suitability of extraction solvent(s) and recovery results obtained with that of the metabolism (%TRRs) studies. Is the method adequate to bracket the expected residue levels. Has the petitioner proposed a confirmatory method or is the method specific (e.g., GC/MS, LC/MS/MS) to the analytes of interest? Was an interference study conducted.]

TABLE C.2.1. Recovery Results from Method Validation of [matrices] using the Enforcement Analytical Method. Standards were prepared in [solvent]			
Matrix	Spiking Level (mg/kg)	Recoveries Obtained	Mean Recovery ± SD (CV)

TABLE C.2.2. Characteristics for the Enforcement Analytical Method Used for the Quantitation of [Chemical] Residues in [Matrices].	
Analyte	
Equipment ID	
Limit of quantitation (LOQ)	
Limit of detection (LOD)	
Accuracy/Precision	[range of percent recoveries ± coefficient of variation (specify range) indicating acceptable/unacceptable accuracy/precision in the range of spiking levels (x).]
Reliability of the Method/ [ILV]	[An independent laboratory method validation [ILV], method No. AAA, was conducted to verify the reliability of method No. AAA for the determination of (pesticide) residues in [matrices]. The values obtained are indicative that method No. is reliable].
Linearity	[The method/detector response was linear (coefficient of determination, r^2= 0.xxx) within the range of xxx - yyy ppm.]
Specificity	[The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest. Peaks were well defined and symmetrical. There appeared to be no carryover to the following chromatograms].

C.3. Independent Laboratory Validation

[Discuss the ILV in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory.]

TABLE C.3.1. Recovery Results Obtained by an Independent Laboratory Validation of the Enforcement Method for the Determination of [Chemical] in [Matrices].			
Matrix	Spiking Level (µg/g)	Recoveries Obtained	Mean Recovery ± SD (CV)

D. CONCLUSION

[Are the methods adequate to quantitate the analytes in matrices for data gathering and have they been adequately validated? If the method is the proposed enforcement method, is it suitable for enforcement? Does the method require regulatory agency validation? This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical(s)] were screened through multiresidue methods [list methods used]. Recoveries were [list method and recovery]. Multiresidue methods [list methods not used] were not screened because [provide rationale]. Multiresidue methods [list methods giving adequate recovery] may be suitable for the analysis of [list analytes].

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the multiresidue method testing data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. MATERIALS AND METHODS

[Provide a brief description of which multiresidue methods were tested. If certain methods were not tested, provide the rationale.]

C. RESULTS AND DISCUSSION

TABLE C.1. Results of Multiresidue Methods Testing with [Chemical].

PAM I Protocol	Results	Comments
A		
B		
C		
D		
E		
F		
G		

D. CONCLUSION

[State whether or not the multiresidue methods are suitable for the analysis of the analyte(s). For the U.S. EPA, include a statement that the data will be forwarded to the U.S. FDA for further evaluation.] This should not be identical to the Executive Summary or Results and Discussion sections.

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

Samples of [ground or whole crop/matrix] spiked with [Chemical name, % a.i., formulation type] at a level of [spiking level] were stored at [temperature] for a duration of [time (days)]. Under these conditions, residues of [parent and/or metabolites] [decreased or increased] by [percentage] in [crop/matrix].

[Briefly describe the method of analysis used to detect residues and whether this method was the same as that outlined in the analytical methodology. Indicate half-life if there is noticeable evidence of degradation.]

The data indicate that residues of [test compound] are stable at [temperature] for [duration of time] in [crop/matrix]. [If the data are sufficient to satisfy agency requirements for translation of demonstrated storage stability to all crops, then so indicate.]

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the storage stability data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapour pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Sample Handling and Preparation

[Briefly describe the spiking procedure, including the solvent used for the standard spiking solution, the concentration, the stability of this solution, the condition of the matrix at the time of spiking (e.g., extract, homogenate, macerate, etc.), the time allowed for equilibrium etc.]

B.2. Analytical Methodology

[If the analytical method is the same as the enforcement or data-gathering method, then reference the method DER and briefly describe analytical method, instrumentation used in determining the residues, and the LOQ. Otherwise, provide a detailed method description.]

C. RESULTS AND DISCUSSION

[Comment on the acceptability of the analytical method for determining residues in the storage stability study.]

[Discuss the storage stability of the analyte(s) during the tested storage intervals. If there is noteworthy dissipation of the analytes, describe qualitatively and quantitatively (provide regression analysis if appropriate).]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte					

FIGURE C.1. ***[Graph of residue stability in matrix as applicable.]***

TABLE C.2. Stability of [Chemical] Residues in [matrix] Following Storage at ___°C.

Commodity	Spike level (mg/kg)	Storage interval (days)	Recovered residues (mg/kg)	Corrected % recovery*
Analyte				

* Corrected for concurrent-recoveries

D. CONCLUSION

[Briefly state the validity of the storage stability study including the impact of experimental design. Has the study demonstrated residue stability in storage? If so, are the data sufficient to

satisfy agency requirements for translation of demonstrated storage stability to all crops? This should not be identical to the Executive Summary or Results and Discussion section.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical name, %a.i., include location of radioactive label] was administered to [(# of animals) species, strain]/dose at dose levels of [x] mg/kg bw/day. Describe how the dose was administered/applied (e.g. oral, dermal, etc.). In a few sentences, describe the extraction and characterization techniques that were used to analyze residues in the various matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study.]

[Indicate whether the parent or metabolite(s) was (were) found to be the predominant residue(s) in the various matrices (include %TRR/matrix). Indicate whether any other metabolites were identified and if any were present at concentrations >10% of the TRRs.]

[Discuss recoveries/account abilities and routes of elimination of radioactivity; absorption and excretion of the compound; radioactivity in organs of concern (distribution/disposition), especially as it relates to sequestration in tissues; extractability; major metabolites; other major factors.]

Supervised irrigated crop trials were conducted [location(s)] in [commodity] at seasonal application rates of [rates] lb a.i./A (kg a.i./ha) with pre-harvest interval(s) of [PHIs]. The results from these trials show that maximum residues are [list commodities and maximum residues at the various rate, PHI, and analyte combinations]. Residue decline data show that [chemical increases/decreases] in [commodities] with increasing pre-harvest intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the residue data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are

needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapour pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Fish Metabolism

TABLE B.1.1.1. General Test Organism Information					
Species	Breed	Age	Weight at study initiation (kg)	Health Status	Description of housing/holding area

TABLE B.1.1.2. Test Organism Dietary Regime		
Diet	Acclimation period	Predosing

TABLE B.1.1.3. Test Organism Dosing Regime				
Regime	Level of administered dose (mg/day)	Food consumption (kg/day)	Vehicle	Timing/Duration
Oral, dermal, aquaculture			capsule, feed, bolus, etc.	

B.1.2. Test Materials

TABLE B.1.2.1. Test Material Characteristics		
Chemical structure	Insert Structure	Insert Structure
Radiolabel position		
Lot No.		
Purity		
Specific activity (Bq)*		

*Bq = desintegration per second

B.1.3. Sampling Information

TABLE B.1.3.1. Sample Collection Information		
Roe	Interval from last dose to sacrifice	Tissues harvested and analyzed
XXX daily	XXX hours	

B.1.4. Analytical Methods for the Identification/ Characterization of Residues

B.1.4.1. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

[If available, include a graphic (i.e., flowchart) of the extraction and fractionation schemes.]

[Briefly describe the extraction, fractionation and hydrolysis strategies for each tissue. The description should including solvents used (ratios), the order of their use, the extraction procedures employed (i.e., blending, maceration, Soxhlet, etc.) and procedures used to release bound and conjugated residues (i.e., acid, base, or enzyme hydrolysis, exhaustive extraction, etc.). Has the petitioner justified the use of severe conditions (e.g., strong acid hydrolysis in the presence of heat, etc.).]

[If applicable, very briefly describe unproductive analytical methodology (i.e., methods that fail to elucidate the nature of the residues or which permit a determination of absence of residues as in protein solubilization methodologies).]

B.1.4.2. Analytical Methodology

[Briefly describe the methods used to identity of the residues (LSC, TLC, GLC, HPLC, etc.)]

B.2. Magnitude of the Residue

B.2.1. Study Site Information

TABLE B.2.1.1. Trial Site Conditions

Trial Identification (City, State/Year)	Soil characteristics				Meteorological data	
	Type	%OM*	pH*	CEC* meq/g	Overall daily/monthly rainfall range	Overall T°C range

* If available.

The actual temperature recordings [*are or are not]* within average historical values for the residue study period. The actual rainfall average *[was or was not]* within the historical rainfall average. Irrigation *[was or was not]* used to supplement as needed. [Explain any meteorological abnormalities that occurred during the conduct of the study].

If TABLE B.2.1.2 is not needed, specify "not applicable" in the first row and delete subsequent rows.

TABLE B.2.1.2 Water Characterization.

Study site	Water characteristics				
	Type	Hardness/Salinity	pH	Turbidity	Dissolved OM

TABLE B.2.1.3. Commodity, Application, and Harvesting Information.

Location (City, State/Year)	EP[1]	Application					Tank Mix Adjuvants
		Treat. No. and Crop Stage at Application	Rate, lb a.i./A (kg a.i./ha)	RTI (days)	Method	Total Rate, lb a.i./A (kg a.i./ha)	

[1] EP = End-use Product
[2] Retreatment Interval

TABLE B.2.1.4. Trial Numbers and Geographical Locations

NAFTA Growing Region	Crop 1			Crop 2			Crop 3		
	Submitted	Requested		Submitted	Requested		Submitted	Requested	
		Canada	US		Canada	US		Canada	US
1									
1A									
2									
3									
4									
5									
5A									
6									
7									
7A									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
Total									

B.2.2. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

B.2.3. Analytical Methodology

[Cite the DER that reviews the method used in this study. Briefly summarize the analytical method, including instrumentation and detectors used to quantify the analytes in the RACs. State LOD and LOQ]

C. RESULTS AND DISCUSSION

[Insert graphical representation of results to highlight trends in the data, if any, and reference all tables in the relevant part of the discussion. This should not be identical to the Executive Summary or Conclusion.]

[Describe the residues in terms of levels, location in the fish matrices (i.e., partitioning into fat vs. muscle etc.). Point out the predominant residues. Note that this is a stand-alone evaluation of the metabolism study. As such, it is not appropriate to discuss residues of concern in this document.]

[Describe the methods used to conduct the metabolism study and to analyze the residues. Discuss any impact that the methods *per se* may have had on the results. Discuss the method's ability to extract the predominant residues from the various fish matrices. Report the accountability. Has the petitioner demonstrated that residues are stable during storage?]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].

Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte				

TABLE C.2. Summary of Storage Conditions [Note: Add rows for analytes as needed.]

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

C.2. Identification, Characterization, and Distribution of Residues

TABLE C.2.1. Total Radioactive Residues (TRRs) in Fish Metabolism Study

Matrix	Specify position of label-1		Specify position of label-2	
	% TRR	ppm	% TRR	ppm

TABLE C.2.2. Quantitative Distribution of the Parent and the Metabolites in Fish Matrices when Dosed with ^{14}C-labeled Test Compound X. [Note: Add rows to the table as needed to accommodate the fractionation/characterization scheme. Create additional Tables C.2.2.x. as needed to accommodate additional radiolabel positions.]

Metabolite Fraction	Matrix 1		Matrix 2		Matrix 3		Matrix 4		Matrix 5	
	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm
Surface wash										
[Add a row for each identified compound]										
[Unidentified compound]										
Organosoluble										
[Add a row for each identified compound]										
[Unidentified compound]										
Aqueous soluble										
[Add a row for each identified compound]										
[Unidentified compound]										

Table C.2.3. **Summary of Characterization and Identification of Radioactive Residues in Fish Matrices Following Application of Radiolabeled [Chemical] at [Rate].** [Note: Create additional Tables C.2.3.x as needed to accommodate additional radiolabel positions.]										
Compound	Muscle		Fat		Kidney		Liver		Roe	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	%TRR	ppm
[Parent]										
[Metabolite 1]										
[Metabolite 2]										
[Metabolite 3]										
[Metabolite 4]										
Total identified										
Total characterized										
Total extractable										
Unextractable (PES)[1]										
Accountability[2]										

[1] Residues remaining after exhaustive extractions.

[2] Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis; see TABLE C.2.1) * 100.

C.3. Proposed Metabolic Profile

FIGURE C.3.1. Proposed Metabolic Profile of [Chemical] in Fish

[Insert metabolic profile]

TABLE C.3.1. Identification of Compounds from Metabolism Study		
Common name/code Figure C.3.1 ID No.	Chemical name	Chemical structure

C.4. Residue Trials

[Reference tables in discussion.]

[Describe the residue values discuss the impact of farming practices and environmental conditions (i.e. soil types, geographical locations, weather conditions, etc.). The discussion should include the adequacy of the number of trials and geographic representation, and any special requirements for harvesting techniques. If residue decline data were submitted with the study, include a description of the behavior of the residue levels across the PHI time span. Do not discuss tolerance levels or harmonization issues in this review.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples in the trials. Include any pertinent information on corrections to residues due to in-storage dissipation.]

TABLE C.4.1. Residue Data from [type of study (irrigated crops, fish, water)] in [commodity] with [chemical].

Trial ID (City, State)	Year	Commodity Variety	Matrix	Formulation	Total Rate lbs a.i./A (kg a.i./ha)	PHI (days)	Residues (ppm)

TABLE C.4.2. Summary of Residue Data from [type of study (irrigated crops, fish, etc.)] with [chemical].

Commodity/Matrix	Total Applic. Rate lb a.i./A (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.

* Highest average field trial value

D. CONCLUSION

[Briefly state the validity of the study, including the impact of the experimental design, any weather/environmental phenomena, and agricultural practices. This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

Residue studies were conducted in [type(s) of establishment] using [mode(s) of application] at application rates of [rates]. [In a few sentences, describe the methods that were used to analyze residues. Also indicate whether or not storage stability has been demonstrated for the samples in the study.] The studies [adequately/did not adequately] address potential residue-transfer routes (e.g., direct deposit, volatilization and sorption/condensation, direct transfer from treated surfaces, transfer through barriers, etc.) The results from these studies show that residues may occur in/on food from treatment in food handling establishments via [list transfer routes]. Maximum observed residues were [list commodities and maximum residues].

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the residue data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient $Log(K_{ow})$		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Study Site and Use Pattern.

Establishment identification	Establishment Type	EP[1]	Application						Residue-transfer Route
			Method	Rate (lb ai/A) (kg ai/ha)	Retreat. Interval (Days)	No. of Applics.	Total Rate (lb ai/A) (kg ai/ha)	Coapplied Adjuvants	

[1]EP = End-use Product

B.2. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

B.3. Analytical Methodology

[Cite the DER that reviews the method used in this study. Briefly summarize the principle of the analytical method used to quantify the analytes in the RACs. State the LOD and LOQ.]

C. RESULTS AND DISCUSSION

[Reference tables in the relevant parts of the discussion.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples from the residue studies. Include any pertinent information on corrections to residues due to in-storage dissipation.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences.]

[Describe the residue values and discuss the impact of method of application, residue barriers, etc. on their magnitude. The discussion should include the adequacy of the number of studies, the types of treatments (space/general/spot/crack and crevice), and the types of food handling establishments that were investigated. Do not discuss tolerance levels or harmonization issues in this review.

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].				
Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte				

TABLE C.2. Summary of Storage Conditions			
Matrix (RAC or Extract)	Storage Temp. (˚C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

TABLE C.3. Residue Data from Food Handling Establishment Residue Studies with [chemical]. **[Note: If corrections to residue values are necessary due to in-storage dissipation, modify the table to list the storage time and the corrected residue values.]**				
Establishment Name and Type	Commodity	Total Rate (lb ai/A) (kg ai/ha)	Method/Transfer Route	Residues (ppm)
Specify Analyte				

TABLE C.4. Summary of Residue Data from Food Handling Establishment Studies with [chemical].										
Commodity	Total Applic. Rate (lb ai/A) (kg ai/ha)	Method/ Transfer Route	Residue Levels (ppm)							
			n	Min.	Max.	HA*	Median (STMdR)	Mean (STMR)	Std. Dev.
Specify Analyte										

* HA = Highest Average.

D. CONCLUSION

[Briefly state the validity of the food handling establishment studies, including the impact of the experimental design. This should not be identical to the Executive Summary or the Results and Discussion section. State whether number and type of commodities tested adequately encompass the range of foods that could be indirectly treated].

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical name] was administered [method of administration] to [number and breed of cattle or poultry] for [duration]. Dosing was made at [listing dosing levels in mg/kg feed]. [In a few sentences, describe the methods that were used to analyze residues in livestock matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study.] Following a preslaughter interval of [xx] days, residues were [list matrices and residue levels]. [Describe, qualitatively and quantitatively, the relationship between residue levels and dosing levels for the matrices addressed in the study.]

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the data depicting residues in livestock are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document. *[Note: For a Canadian or joint review, include an appendix that shows the livestock dietary burden calculations as they apply to this submission. For an EPA-only review, the dietary burden should appear in the summary document only.]*

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add columns as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Livestock

TABLE B.1.1. Description of Livestock Used in the Feeding Study.					
Species	Breed	Age	Weight at study initiation (kg)	Health status	Description of housing/holding area

TABLE B.1.2. Test Animal Dietary Regime

Composition of Diet	Feed consumption (kg/day)	Water	Acclimation period	Predosing

TABLE B.1.3. Dosing Regime.

Treatment group	Treatment Type	Level of administered dose (mg/day)	Residue intake in diet (ppm)	Vehicle	Timing/ Duration

TABLE B.1.4 Sample Collection.

Milk/Eggs collected	Amount of milk and number of eggs produced during normal production	Urine, feces and cage wash collected	Interval from last dose to sacrifice (days)	Tissues harvested and analysed

B.2. Sampling Handling and Preparation

[Briefly describe how samples were handled after havesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

B.3. Analytical Methodology

[Briefly describe the analytical method including instrumentation and detection used in determining the residues].

C. RESULTS AND DISCUSSION

[Insert graphical representation of results to highlight trends in the data, if any, and reference all tables in the relevant part of the discussion. This should not be identical to the Executive Summary or Conclusion.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples in the crop field trials. Include any pertinent information on corrections to residues due to in-storage dissipation.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control

samples of various crop matrices are free from interferences.]

[Discuss the residue values, including the impact of any abnormal study conditions. Discuss the feeding level/tissue residue relationship. Is it linear for the entire range of tested feeding levels or only a subset of those levels. How does the relationship impact the estimation of tissue residues from a specific feeding level? Note that this is a stand-alone evaluation of the feeding study. As such, it is not appropriate to discuss tolerance levels or harmonization issues in this document. Such topics will be covered in the residue chemistry cover memo that accompanies the data volume(s) associated with this chemical's submission(s).]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].

Matrix	Analyte	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev

TABLE C.2. Summary of Storage Conditions

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

TABLE C.3. Residue Data from [ruminant/poultry] Feeding Study with [chemical].

Animal identication #	Matrix/Collection Time	Feeding Level (ppm)	Residues (ppm)

TABLE C.4. Summary of Residue Data from [ruminant/poultry] Feeding Study with [chemical].

Matrix	Feeding Level (ppm)	Residue Levels (ppm)					
		n	Min.	Max.	Median (STMdR)	Mean (STMR)	Std. Dev.

FIGURE C.1. ***[Chemical]*** **residues in [whole milk/eggs] as a Function of Time. Residues are average values for each treatment group.**

[insert graph]

FIGURE C.2. Linear Regression of Residues on Feeding Level

[insert graphs for each tissue]

TABLE C.5. Summary of residues of [Chemical] in [whole milk/eggs] and tissues of a [species] from the depuration study.			
Matrix	Study Day	Animal #	Residue (ppm)

FIGURE C.3. Depuration curve for residues of [Chemical] in [whole milk /eggs].

D. CONCLUSION

[Briefly state the validity of the study and the relationships between residue values in the livestock commodities and residue levels in feed. This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

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Appendix 1. Livestock Dietary Burden Calculations [NB: Do not include this appendix for an EPA-only review. For EPA, the calculations appear in the Residue Chemistry Summary Document].

Example

				% of Diet Used				Dietary Burden, ppm			
Crop	Commodity	Residue	%DM	Beef	Dairy	Poultry	Swine	Beef	Dairy	Poultry	Swine
Barley	Grain	0.5	88	50	40	75	80	0.3	0.2	0.4	0.4
Corn, field	Milled byproducts	0.5	85	50	25	0	0	0.3	0.1	0.0	0.0
Alfalfa	Forage	0.3	35	0	0	25	20	0.0	0.0	0.1	0.1
Alfalfa	Meal	0.3	89	0	35	0	0	0.0	0.1	0.0	0.0
			Total	**100**	**100**	**100**	**100**	**0.6**	**0.4**	**0.5**	**0.5**

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Petitioner/Registrant] has submitted field trial data for [active ingredient] on [crop]. [Number of field trials] trials were conducted encompassing Regions [List Regions and State or Province; # of trials] during the [year] growing season. The number and locations of field trials [are or are not] in accordance with OPPTS Guideline 860.1500 and Directive 98-02; Section 9.

At each test location, [describe timing and method of application; formulation used, rate, treatment interval and seasonal application rates of [rates] lb a.i./A (kg a.i./ha)]. An adjuvant [was or was not] added to the spray mixture for all applications. [Crops] were harvested at [state PHIs].

[In a few sentences, describe the method used to analyze the residues and its acceptability as a data-gathering method. Note whether or not residues of the chemical have been shown to be stable for the duration of storage that occurred during the conduct of this study.] The results from these trials show that maximum residues are [list commodities and maximum residues at the various rate, PHI, and analyte combinations]. Residue decline data show that [chemical increases/decreases] in [commodities] with increasing pre-harvest intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's

Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/(EP)	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapour pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1 Trial Site Conditions

Trial Identification (City, State/Year)	Soil characteristics				Meteorological data	
	Type	%OM*	pH*	CEC* meq/g	Overall daily/monthly rainfall range	Overall T°C range

*These parameters are optional except in cases where their value affects the use pattern for the chemical.

The actual temperature recordings *[are or are not]* within average historical values for the residue study period. The actual rainfall average *[was or was not]* within the historical rainfall average. Irrigation *[was or was not]* used to supplement as needed. [Explain any meteorological abnormalities that occurred during the conduct of the study.]

TABLE B.1.2. Study Use Pattern.

Location (City, State/Year)	EP [1]	Application					Tank Mix Adjuvants	Harvest Procedures [4]
		Method/Timing	Vol, GPA[2]	Rate, (lb a.i./A) (g a.i./ha)	RTI, [3] days	Total Rate, (lb a.i./A) (g a.i./ha)		
		1. List each application separately. Expand or contract the number of rows as needed.						
		2.						
		3.						

[1]EP = End-use Product
[2] Gallons per acre, L/ha
[3] Retreatment Interval
[4] Only applicable for cotton commodities.

TABLE B.1.3. Trial Numbers and Geographical Locations

NAFTA Growing Region	Crop 1			Crop 2			Crop 3		
	Submitted	Requested		Submitted	Requested		Submitted	Requested	
		Canada	US		Canada	US		Canada	US
1									
1A									
2									
3									
4									
5									
5A									
5B									
6									
7									
7A									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
Total									

B.2. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

B.3. Analytical Methodology

[Cite the DER that reviews the method used in this study. Briefly summarize the principle of the analytical method used to quantify the analytes in the RACs. State the LOD and LOQ.]

C. RESULTS AND DISCUSSION

[Reference tables in the relevant parts of the discussion.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples in the crop field trials. Include any pertinent information on corrections to residues due to in-storage dissipation.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences.]

[Describe the residue values. Discuss the impact of farming practices and environmental conditions (i.e. soil types, geographical locations, weather conditions, etc.). The discussion should include the adequacy of the number of trials and geographic representation, and any special requirements for harvesting techniques. If residue decline data were submitted with the study, include a description of the behavior of the residue levels across the PHI time span. Do not discuss tolerance levels or harmonization issues in this review.]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].

Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte				

TABLE C.2. Summary of Storage Conditions [Note: Add columns for analytes as needed.]

Matrix (RAC or Extract)	Storage Temp. (˚C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

TABLE C.3. Residue Data from Crop Field Trials with [chemical]. [Note: If corrections to residue values are necessary due to in-storage dissipation, modify the table columns "Residue 2 (ppm)" and "Residue 3 (ppm)" to list the storage time and the corrected residue values.]

Trial ID (City, State/Year)	Region	Crop/ Variety	Commodity or Matrix	Total Rate, (lb a.i./A) (kg a.i./ha)	PHI (days)	Residues 1 (ppm)	Residues 2 (ppm)	Residues 3 (ppm)

TABLE C.4. Summary of Residue Data from Crop Field Trials with [chemical].

Commodity	Total Applic. Rate, (lb a.i./A) (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Specify analyte									

* HAFT = Highest Average Field Trial.

D. CONCLUSION

[Briefly state the validity of the crop field trials, including the impact of the experimental design, any weather/environmental phenomena, and agricultural practices. This is not equivalent to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
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PC Code:

Template Version September 2003

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical name, % a.i., formulation type] was applied to [crop] at [rate of application (g a.i./ha)]. The [RAC samples] were processed into [processed food/feed fractions]. [In a few sentences, describe the analytical method that was used to analyze residues in the RAC and processed matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study.] A comparison of the residues in the RAC with those in each processed fraction resulted in concentration factors of [concentration factors] for [processed fractions], respectively. These concentration factors [conform/did not conform] with the theoretical concentration factors.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the processed commodity residue data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

TABLE B.1.2. Study Use Pattern [Insert appropriate entries from field trial DER].

Location (County, State/Year)	EP [1]	Application					Tank Mix Adjuvants	Harvest Procedures [4]
		Method/Timing	Vol, GPA[2]	Rate, (lb a.i./A) (g a.i./ha)	RTI, [3] days	Total Rate, (lb a.i./A) (g a.i./ha)		
		1. List each application separately. Expand or contract the number of rows as needed.						
		2.						
		3.						

[1]EP = End-use Product
[2] Gallons per acre, L/ha
[3] Retreatment Interval
[4] Only applicable for cotton commodities.

B.2. Sample Handling and Processing Procedures

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

FIGURE 1. Processing Flowchart for [RAC].

[Insert flowchart figure(s) that describe the steps taken to produce the processed commodities.]

B.3. Analytical Methodology

[Briefly describe the principle of the analytical method including sample preparation and instrumentation, detection used in determining the residues. State LOD and LOQ.]

C. RESULTS AND DISCUSSION

[Reference tables in the relevant part of the discussion.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples in the processing study. Include any pertinent information on corrections to residues due to in-storage dissipation.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences and/or discuss any apparent residues

in control samples. The discussion should include a comparison to typical commercial practices and the suitability of the analytical method.]

[Compare the empirical processing factors to theoretical processing factors. Note that this is a stand-alone evaluation of the field trials. As such, it is not appropriate to discuss tolerance levels or harmonization issues in this document. Such topics will be covered in the residue chemistry cover memo that accompanies the data volume(s) associated with this chemical's submission(s).]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].				
Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte				

TABLE C.2. Summary of Storage Conditions			
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

Table C.3. Residue Data from [RAC] Processing Study with [chemical].					
RAC	Processed Commodity	Total Rate (lb a.i./A) (g a.i./ha)	PHI (days)	Residues (ppm)	Processing Factor

D. CONCLUSION

[Briefly state the validity of the study and the extent to which residues concentrate in processed commodities. This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

[Chemical name, % a.i., formulation type] was applied to [crop] at [rate of application (g a.i./ha)]. The [RAC samples] were processed into [processed food/feed fractions]. [In a few sentences, describe the analytical method that was used to analyze residues in the RAC and processed matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study.] A comparison of the residues in the RAC with those in each processed fraction resulted in concentration factors of [concentration factors] for [processed fractions], respectively. These concentration factors [conform/did not conform] with the theoretical concentration factors.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the processed commodity residue data are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

TABLE B.1.2. Study Use Pattern [Insert appropriate entries from field trial DER].

Location (County, State/Year)	EP [1]	Application					Tank Mix Adjuvants	Harvest Procedures [4]
		Method/Timing	Vol, GPA[2]	Rate, (lb a.i./A) (g a.i./ha)	RTI, [3] days	Total Rate, (lb a.i./A) (g a.i./ha)		
		1. List each application separately. Expand or contract the number of rows as needed.						
		2.						
		3.						

[1]EP = End-use Product
[2] Gallons per acre, L/ha
[3] Retreatment Interval
[4] Only applicable for cotton commodities.

B.2. Sample Handling and Processing Procedures

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

FIGURE 1. Processing Flowchart for [RAC].

[Insert flowchart figure(s) that describe the steps taken to produce the processed commodities.]

B.3. Analytical Methodology

[Briefly describe the principle of the analytical method including sample preparation and instrumentation, detection used in determining the residues. State LOD and LOQ.]

C. RESULTS AND DISCUSSION

[Reference tables in the relevant part of the discussion.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples in the processing study. Include any pertinent information on corrections to residues due to in-storage dissipation.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences and/or discuss any apparent residues

in control samples. The discussion should include a comparison to typical commercial practices and the suitability of the analytical method.]

[Compare the empirical processing factors to theoretical processing factors. Note that this is a stand-alone evaluation of the field trials. As such, it is not appropriate to discuss tolerance levels or harmonization issues in this document. Such topics will be covered in the residue chemistry cover memo that accompanies the data volume(s) associated with this chemical's submission(s).]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].				
Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte				

TABLE C.2. Summary of Storage Conditions			
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

Table C.3. Residue Data from [RAC] Processing Study with [chemical].					
RAC	Processed Commodity	Total Rate (lb a.i./A) (g a.i./ha)	PHI (days)	Residues (ppm)	Processing Factor

D. CONCLUSION

[Briefly state the validity of the study and the extent to which residues concentrate in processed commodities. This should not be identical to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
Petition Number(s):
DP Barcode(s):
PC Code:

Primary Evaluator	[Evaluator name, title, and affiliation]	Date:
Peer Reviewer	[Peer Reviewer name, title, and affiliation]	Date:
Approved by	[Approver name, title, and affiliation]	Date:

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

STUDY REPORTS:

MRID No. Authors (Date) Study title: Lab Project Number: xxxx. Unpublished study prepared by XXXX. nnn pages. If the citation is a published study, list authors, date, title, journal, volume (issue): page range.

EXECUTIVE SUMMARY:

Chemical name, [% a.i., formulation type] was applied to soil [indicate soil type] at [rate of application] lb a.i./A (kg a.i./ha). [Rotational crops] were planted at a number of time intervals post-treatment (days after treatment; DAT): x1, x2, x3 and x4 DAT. [In a few sentences, describe the method used to analyze the residues and its acceptability as a data-gathering method.] [Note whether or not residues of the chemical have been shown to be stable for the duration of storage that occurred during the conduct of this study.] [Indicate at which plant-back interval the maximum residues occurred. Note if there are any environmental or agricultural practices that influenced the residues in rotated crops.]

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the data depicting residues in rotational crops are classified as scientifically [acceptable/unacceptable]. [List any scientific deficiencies or clarifications that are needed.]

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode Dxxxxxx] and in Canada's Regulatory Decision Document.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements [were/ were not] provided. [Discuss deviations from regulatory requirements, including whether or not they impact the validity of the study.]

A. BACKGROUND INFORMATION

[Give background information on the active ingredient, its mode of action, and the purpose of the end-use product (one paragraph).]

TABLE A.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound [Note: add rows as needed]		
Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__˚C)		
Solvent solubility (mg/L at __˚C)		
Vapour pressure at __˚C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log(K_{ow})		
UV/visible absorption spectrum		

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1 Trial Site Conditions

Trial Identification (City, State/Year)	Soil characteristics				Meteorological data	
	Type	%OM*	pH*	CEC* meq/g	Overall daily/monthly rainfall range	Overall T°C range

*These parameters are optional except in cases where their value affects the use pattern for the chemical.

The actual temperature recordings *are or are not* within average historical values for the residue study period. The actual rainfall average *was or was not* within the historical rainfall average. Irrigation *was or was not* used to supplement as needed. Explain any meteorological abnormalities that occurred during the conduct of the study.

TABLE B.1.2. Study Use Pattern.

Location (City, State/Year)	EP [1]	Application					Tank Mix Adjuvants	Harvest Procedures [4]
		Method/Timing	Vol, GPA[2]	Rate, (lb a.i./A) (g a.i./ha)	RTI, [3] days	Total Rate, (lb a.i./A) (g a.i./ha)		
		1. List each application separately. Expand or contract the number of rows as needed.						
		2.						
		3.						

[1]EP = End-use Product
[2] Gallons per acre, L/ha
[3] Retreatment Interval
[4] Only applicable for cotton commodities.

B.2. Sample Handling and Preparation

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and any preparation that was done prior to extraction.]

B.3. Analytical Methodology

[Cite the DER that reviews the method used in this study. Briefly summarize the analytical method used to quantify the analytes in the RACs. State LOD and LOQ. If the analytical methods differ significantly from reviewed data-gathering or enforcement methods, provide a complete description of the method.]

C. RESULTS AND DISCUSSION

[Reference tables in the relevant part of the discussion.]

[Discuss whether or not the storage stability study (cite the DER) supports the storage durations/conditions of samples in the rotational crop trials. Include any pertinent information on corrections to residues due to in-storage dissipation.]

[Briefly comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences.]

[Discuss the residue values, including, if applicable, the impact of farming practices and environmental conditions (i.e. soil types, geographical locations, weather conditions, etc.). Indicate whether or not temperature and precipitation were within average historical values for the residue study period and if irrigation was used to supplement rainfall as needed. Describe how the residue levels behave with respect to the plant-back intervals included in the study. Have at least 2 trials been done on a representative root and tuber vegetable, small grain, and leafy vegetable crops (soybeans may be substituted for the leafy vegetable)? Do not discuss tolerance levels or harmonization issues in this review.]

TABLE C.1. Summary of Concurrent Recoveries of [Chemical] from [matrix].

Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Analyte				

TABLE C.2. Summary of Storage Conditions

Matrix (RAC or Extract)	Storage Temp. (˚C)	Actual Storage Duration (days or months)	Interval of Demonstrated Storage Stability (days or months)

TABLE C.3. [Chemical] Residues in Rotational Crops.								
Trial ID (City, State/Year)	Region	Crop/ Variety	Commodity	Total Rate, (lb a.i./A) (kg a.i./ha)	Harvest DAP[1]	PBI[2] (days)	Residues 1 (ppm)	Residues 2 (ppm)

[1] DAP = Days After Planting
[2] PBI = Plant Back Interval.

TABLE C.4. Summary of Residue Data in Rotational Crops Following Primary Treatment with [chemical].									
Commodity	Applic. Rate, (lb a.i./A) (kg a.i./ha)	PBI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Analyte									

* HAFT = Highest Average Field Trial.

D. CONCLUSION

[Briefly state the validity of the field accumulation in rotational crop studies, including the impact of the experimental design, any weather/environmental phenomena, and agricultural practices. This is not equivalent to the Executive Summary or Results and Discussion sections.]

E. REFERENCES

F. DOCUMENT TRACKING

RDI: Name1 (Date); Name2 (Date); Name3 (Date); etc.
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Template Version September 2003